AUG 2 4 2000

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

510(k) Number: TBD K001666

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Applicant Information:

Date Prepared:	January 1, 1999
Name:	Intuitive Surgical, Inc.
Address:	1340 W. Middle field Road Mountain View, California 94043
Contact Person:	David Casal, Ph.D.
Phone Number:	650-237-7013
Facsimile Number:	650-526-2060
e-mail:	david_casal@intusurg.com

Device Information:

Classification:	Class II	Endoscope and Accessories Rigid Endoscope Gynecologic Laparoscope and Accessories
Trade Name:	Intuitive Surgical™ Instruments / Accessories: Endoscopic Instruments including: Stereo Endoscope and accessories for use with: The Intuitive Surgical™ Endoscopic Instrument Control System	
Common Name:	3D Endoscope and Accessories	
Classification Name:	Endoscope and Accessories	21 CFR §876.1500
	Rigid Endoscope	21 CFR §876.1500
	Gynecologic Laparoscope/Accessories	21 CFR §884.1720

Predicate Device:

The Intuitive Surgical™ Endoscope is substantially equivalent in intended use and/or method of operation to the following predicate device:

The Intuitive Surgical™ Stereo View Endoscopic System (K990188)

Device Description:

The Intuitive Surgical™ Stereo View System consists of an Intuitive Surgical endoscope, an Intuitive Surgical camera, and a commercially available light source. The endoscope is essentially identical in size and shape to the predicate device referenced above, but built by a different manufacturer. The camera and illumination sources attach to the endoscope and are essentially identical in function to those described for the predicate device.

Intended Use:

The Intuitive Surgical™ Stereo View Endoscopic System is intended for endoscopic viewing of internal surgical sites during minimally invasive surgery in the peritoneal cavity, thoracic cavity, and peritoneum. It is designed to be used with the Intuitive Surgical™ Endoscopic Instrument Control System during thoracoscopic and laparoscopic surgical procedures.

Comparison to Predicate Devices:

The basic design and function of the Intuitive Surgical™ Stereo View Endoscopic System is essentially identical in terms of shape, size, materials, and function to the predicate device, but built by a different manufacturer. The illuminator (light source) and light guide are similar in function to those described in the predicate system.

Test Data:

Design analysis and comparison confirm that basic functional characteristics are substantially equivalent to the predicate device cited. Components of the Intuitive Surgical™ Stereo View Endoscopic System are manufactured using materials that are identical to materials used in the predicate device that have a long history of human contact bio-compatibility. Where applicable, electrical components of the Intuitive Surgical™ Stereo View Endoscopic System have been tested to ensure compliance with safety characteristics described in standards from UL 544, UL 2601-01, CSA C22.2, UL544, EN 55011, IEC 601-1 and IEC 601-1-2 as well as relevant provisions of the European Medical Device Directive 93/42/EEC. The biocompatibility of materials used in the subject device is also consistent with standards for human use as described in ISO 10993.

Summary:

Based upon the product technical information provided, intended use, and performance information provided in this pre-market notification, the Intuitive Surgical Stereo View Endoscopic System has been shown to be substantially equivalent to a currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2000

David Casal, Ph.D.
Vice President, Clinical, Regulatory and Quality Affairs
Intuitive Surgical, Inc.
1340 West Middlefield Road
Mountain View, California 94043

Re: K001666
Trade Name: Intuitive Surgical™ Instruments/Accessories: Endoscopic Instruments including: Stereo Endoscope and accessories for use with: The Intuitive Surgical™ Endoscopic Instrument Control System
Regulatory Class: II
Product Code: GCJ
Dated: May 30, 2000
Received: May 31, 2000

Dear Dr. Casal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K001666

Device Name: Intuitive Surgical™ Stereo View Endoscopic System

Indications for Use:

The Intuitive Surgical™ Stereo View Endoscopic System is intended for endoscopic viewing of internal surgery sites during minimally invasive surgery in the peritoneal cavity, thoracic cavity, and peritoneum. It is designed to be used with the Intuitive Surgical™ Endoscopic Instrument Control System during thoracoscopic and laparoscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001666

Prescription Use X OR Over-the Counter Use_____
(per 21 CFR §801.109)

(Optional Format 1-2-96)